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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce House of Representatives

February 1986

FOOD INSPECTIONS

FDA Should Rely More on State Agencies

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February 18, 1986

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

In August 1984, we reported to your Subcommittee[1] on the nationwide sanitation conditions of food manufacturing establishments. We pointed out that the Food and Drug Administration (FDA) was inspecting establishments with little or no involvement in interstate commerce and concluded that such establishments may be more appropriately subject to routine inspection by state or local governments. In December 1984 we contacted state inspection agencies and determined that they play a significant role in regulating the sanitation conditions of food manufacturers. In view of this role, we believe FDA could place greater reliance on state agencies for inspecting many of the establishments in its current inventory. Your office requested a report on the results of this follow-up work.

In our August 1984 report we pointed out that FDA inspection records for a nationwide sample of 152 establishments showed that 85 (or 56 percent) had interstate sales of 10 percent or less. Of the 152 establishments, 52 (or 34 percent) had indicated that they had no interstate sales. Some of them also had small estimated annual sales. We recommended that FDA continue to review its food manufacturing inventory and remove establishments with little or no involvement in interstate commerce and make appropriate resource adjustments unless it found a compelling need for continued inspection.

FDA officials advised us that resource limitations prevented it from reviewing its complete inventory to establish a basis for including establishments with limited interstate sales but did agree to review the 85 establishments with interstate sales of 10 percent or less. In responding to our report in December 1984, the Department of Health and Human Services (HHS) said FDA determined that 69 of the establishments (or 81 percent) should remain in its active inventory. HHS cited a number of reasons—such as consumer complaints, labeling problems, and the

[1]Evaluation of Selected Aspects of the Food and Drug Administration's Food Manufacturing Sanitation Inspection Efforts (GAO/HRD-84-65, Aug. 30, 1984).

potential for sanitation, bacterial, and pesticide problems—as a basis for FDA's continued inspection of these firms (see pp. 4 and 5). In making this determination, however, FDA did not contact state inspection agencies to ascertain their responsibility for conducting routine sanitation inspections or the frequency and results of inspections for the 85 establishments.

Information we obtained from state inspection agencies (see app. I) on the 69 establishments showed that 57 were routinely inspected by state agencies on an average of every 7 months and that the state agencies were identifying establishments with serious or very serious insanitary conditions. In view of the significant state coverage of these establishments, low estimated annual sales of some of them, and their limited involvement in interstate commerce, we continue to believe that routine FDA inspections of most of these establishments is not warranted and that they should be removed from FDA's active inventory. Moreover, FDA should contact states to identify other establishments that should be removed from its inventory based on these factors. In doing so, FDA should also determine the states' policy and frequency for conducting food sanitation inspections.

Background

FDA is the primary federal regulatory agency charged with the safety and quality of the nation's food supply. If the food (except for meat and poultry products, which are regulated by the Department of Agriculture) is involved in interstate commerce, it is under FDA's jurisdiction. FDA derives its authority over industry food sanitation practices from the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938, as amended (21 U.S.C. 301). The act prohibits the receipt or shipment of food across state borders if it is adulterated with filthy, putrid, or decomposed substances.

In addition, each state has its own statutes, regulations, and institutions concerned with regulating the quality and safety of food products and has the authority to inspect all food establishments within state boundaries. According to FDA, the states have the greatest capability, interest, and authority in the food sanitation area. FDA contracts with state agencies to conduct sanitation inspections of certain establishments and provides training and technical assistance to state and local governments. FDA's Acting Director, Office of Regional Operations, advised us that state food sanitation requirements are generally equivalent to FDA's requirements.

FDA monitors the sanitation conditions of food establishments principally through inspections and provides assurances to consumers that the food industry is meeting its responsibility of producing safe products. FDA does not specify the frequency with which food sanitation inspections should be conducted but selects establishments for inspection based on such factors as products produced, the violative rate of an establishment or an industry, and whether FDA has ever inspected an establishment. FDA requires each of its 23 field offices to maintain an inventory of food, drug, cosmetic, and medical device establishments subject to inspection under the FD&C Act. FDA uses this inventory as the principal basis for allocating planned inspections and inspection resources to its field offices. The inventory is also used in budget presentations to HHS, the Office of Management and Budget, and the Congress to justify current and additional resources.

In fiscal year 1986, FDA requested for the food sanitation program $49.2 million, which represents 43 percent of the Center for Food Safety and Applied Nutrition's $114 million budget and 12 percent of FDA's $409 million total budget. This was about the same level of resources committed to the program in fiscal year 1985.

GAO Questioned Basis for Inspecting Firms With Limited Interstate Sales

In August 1984 we reported on (1) the nationwide sanitation conditions of food manufacturing establishments and (2) FDA's efforts to improve the accuracy of its food establishment inventory and to ensure that the establishments selected for routine inspection were reasonable for FDA regulation considering their percentage of interstate sales.

To assess the sanitary conditions in the food manufacturing industry, between February and June 1983 FDA inspected for us a nationwide sample of 152 establishments from its food establishment inventory. FDA classified the seriousness of insanitary conditions for the 152 inspections. Ninety-three percent of the establishments did not have significant sanitation problems.

Our report noted that between July 1982 and January 1984, FDA's removal of 12,776 (or 34 percent) of the 38,077 food manufacturers, such as small retail bakeries, from its food establishment inventory helped improve the inventory's accuracy. However, our nationwide sample of food manufacturing establishments indicated opportunities for FDA to further reduce its inventory. Over half of the establishments (85) in our sample had 10 percent or less interstate sales, and 52 of

these had no interstate sales. Based on our nationwide sample, we estimated that 6,473 firms remaining in FDA's inventory had interstate sales of 10 percent or less.

We concluded that routine inspections of these establishments should be left to state and local governments unless FDA found a compelling need to keep such establishments in its inventory. We also concluded that with further reductions in its inventory, FDA had an opportunity to review its level of resources devoted to food sanitation and quality control and consider how such resources might be better used in other program areas.

Our report recommendations addressed these issues. Although FDA agreed in principle with our recommendations, it advised us that resource limitations prevented establishing a special project requiring field offices to review the entire inventory. FDA did agree to review the 85 establishments with interstate sales of 10 percent or less that were in our nationwide sample.

FDA Believes Most Establishments Should Remain in Inventory

On December 12, 1984, HHS advised us that 69 of the 85 establishments with little or no interstate sales should remain in FDA's inventory and continue to be routinely inspected. Sixteen establishments were deleted from FDA's inventory, including those that were retail stores or did not ship food products interstate. However, FDA justified keeping 69 establishments in its inventory because they

- had a large volume of business;
- received and/or shipped goods in interstate commerce;
- produced products that had the potential for bacterial, sanitation, and pesticide problems;
- had a history of insanitary conditions;
- conducted interstate business indirectly through other establishments that ship goods interstate; or
- were subject to consumer complaints and labeling problems involving food and color additives (see app. II).

According to HHS, FDA had previously removed thousands of establishments from its inventory because they had limited interstate sales. However, HHS commented that all establishments should not be removed from the inventory solely on that basis. FDA officials advised us that they are not entitled by law to information regarding an establishment's sales volume or volume of interstate commerce. FDA stated that data on

both total sales and interstate sales are provided voluntarily by the regulated industry, and FDA cannot assume their accuracy. According to FDA, it cannot place too much emphasis on this single criterion for routine inspectional coverage. FDA agreed, however, that the amount of interstate business should be among the factors used in selecting firms for inspection.

State Agencies Routinely Inspect Establishments in FDA's Inventory

On December 20, 1984, we sent questionnaires (see app. V) to 27 jurisdictions (26 states and Puerto Rico) requesting information on (1) state food inspection policies and (2) the frequency and results of state inspections for the 69 establishments FDA believed should remain in its inventory subject to routine inspection. These 69 establishments were located in the 27 jurisdictions.

All 27 jurisdictions reported that they routinely conduct sanitation inspections of food manufacturers. Such inspections are required by state law in 14 states and Puerto Rico and by state regulation or policy in 9 other states. In the other three states, routine food sanitation inspections are required by both state law and agency policy. An FDA report that contains a summary of state laws shows that basic state food laws and amendments in 49 states are patterned after federal food laws.

The frequency of state inspections depended on the type of establishment, the potential health risk involved, or the firm's inspection history. Twenty-one states and Puerto Rico indicated that they inspect establishments at least once a year, while four other states indicated that the frequency depends on the history of the firm or health risk. Only one state did not conduct yearly inspections.

Information provided by the states and Puerto Rico on 59 of the 69 establishments[2] (see app. III) showed that during the past 3 years, 57 were inspected a total of 294 times, or more than once a year. The other two establishments were known to state agencies but had not been inspected. Of these 57 establishments, 23 had one or more routine inspections where serious or very serious sanitation problems were noted. In total these 23 establishments were inspected 154 times, with 77 inspections disclosing serious or very serious problems.

[2]Ten establishments were not subject to state inspection: (1) three were out of business, (2) five were subject to local or county inspections, and (3) two were unknown to the state agency but were to be inspected as soon as possible. Of the other 59 establishments, 57 (97 percent) were inspected by state agencies (see p. 17).

FDA, in responding to our August 1984 report, cited insanitary conditions as support for retaining 8 of 59 establishments with little or no interstate sales in its inventory. Six FDA inspections at three of these establishments disclosed serious or very serious sanitation problems. All eight establishments were inspected by state agencies—three were inspected a total of 16 times in the last 3 years and had no or only minor sanitation problems, and five were inspected a total of 28 times by the states, with 21 inspections indicating serious or very serious sanitation problems.

States inspected establishments with serious or very serious sanitation problems almost twice as frequently as those without serious problems. The 23 establishments with serious or very serious sanitation problems were inspected on the average every 5 months; the 34 without serious problems were inspected on the average every 9 months. Table 1 shows the total number of state inspections and corresponding inspection results for 23 establishments having serious or very serious insanitary conditions during 1982-84.

Table 1: Firms in Which at Least One State Inspection Found Serious or Very Serious Conditions

Firm	Number of state inspections	Insanitary conditions None	Minor[a]	Serious[b]	Very serious[c]
A	10	1	1	5	3
B	5	•	3	2	•
C	2	•	1	1	•
D	5	3	1	1	•
E	6	•	5	1	•
F	1	•	•	1	•
G	6	•	4	2	•
H	9	1	6	2	•
I	3	•	2	1	•
J	3	1	1	1	•
K	6	1	•	3	2
L	5	•	1	3	1
M	8	•	•	3	5
N	8	•	1	5	2
O	9	•	1	5	3
P	9	•	•	•	9
Q	7	1	•	6	•
R	13	3	8	2	•
S	4	•	3	1	•
T	3	•	2	1	•
U	10	•	6	4	•
V	11	3	7	1	•
W	11	2	8	1	•
	154	**16**	**81**	**52**	**25**

[a]Not likely to cause product adulteration.

[b]Could reasonably result in or have potential for causing product adulteration.

[c]Have immediate potential or have caused product adulteration.

According to FDA inspection reports, eight establishments had estimated annual sales of less than $100,000 and remain in FDA's inventory subject to routine inspection. These establishments were inspected a total of 41 times over a 3-year period by state agencies. The operations and inspections of four of these establishments are described below.

1. A small winery, according to FDA's 1983 inspection reports, had estimated annual sales of less than $25,000. The winery produced about 10,000 gallons per year with estimated interstate sales of about 10 percent. The state had inspected the winery yearly for the past 3 years and found minor insanitary conditions. A May 1983 FDA inspection revealed

no insanitary conditions. FDA justified continued inspection of this winery based on some interstate sales and a potential for pesticide problems. A state official advised us that the state does pesticide inspections. State law requires annual inspection of food manufacturing establishments.

2. Another winery, also having estimated annual sales of less than $25,000, produced about 1,500 gallons of red wine per year from grapes obtained from the owner's vineyard. A May 1983 FDA inspection indicated no insanitary conditions and interstate sales of 1 percent. Distribution of the wine was primarily to local restaurants and cheese shops. The winery was inspected in 1981 and 1983 by the state. No insanitary conditions were noted in 1981, and minor insanitary conditions were found in 1983. State law requires annual inspection of food manufacturing establishments. FDA justified keeping this establishment in its inventory based on interstate business.

3. A small bakery had estimated annual sales of between $50,000 and $100,000. An April 1983 FDA inspection disclosed minor insanitary conditions. The inspection report showed that no products were shipped interstate and that 50 percent of the bakery's products were sold to local restaurants, hotels, and caterers. The remaining products were sold through the bakery's retail outlet. The state inspected the establishment eight times between January 1982 and March 1984. Two inspections indicated very serious insanitary conditions, five indicated serious conditions, and one indicated minor conditions. State law and agency policy require food sanitation inspections as "needed." FDA stated that because 50 percent of the bakery's business was wholesale business and it received goods in interstate shipments, routine FDA inspection of the establishment should continue.

4. A manufacturer of oriental noodles had estimated annual sales of between $25,000 and $50,000. An April 1983 FDA inspection disclosed no insanitary conditions. The inspection report stated that the establishment did not ship products interstate but did receive raw materials in interstate commerce. The state inspected the establishment nine times between February 1982 and March 1984. Seven inspections disclosed minor sanitation problems, and two found no problems. State law requires food sanitation inspections every 6 months. FDA justified continued inspection based on a potential for bacterial problems.

Appendix IV contains other examples of establishments that FDA retained in its inventory. These establishments were also inspected by state agencies.

Conclusions

In view of the states' significant role in regulating the sanitation conditions of food manufacturers, we believe that FDA can rely more on state governments for inspection of many of the establishments in its current inventory. FDA should review its inventory of food establishments with interstate sales of 10 percent or less to determine which could be removed from its inventory, considering state coverage, estimated annual sales volume, and sanitation problems identified during previous state and FDA inspections. Also, FDA should consider sampling establishments with interstate sales of over 10 percent, again considering state responsibility for coverage and previous inspections, to determine if some of these establishments could be removed from its inventory.

FDA's review of its inventory should include contacts with state inspection agencies to determine their policies for and frequency of inspecting food establishments and to obtain information on the insanitary conditions noted during previous state inspections. Establishments operating under sanitary conditions with limited or no interstate sales and small sales volume should be left to the states for future inspection. An FDA/state strategy could be developed for future inspections of establishments with a history of serious and very serious insanitary conditions to help assure these establishments are in compliance with applicable food laws and regulations.

We agree with FDA that food establishments should not be removed from the inventory based on a single criterion, such as limited interstate sales. However, it is questionable whether FDA should continue inspecting such establishments when they are also being routinely inspected by state agencies, have small estimated annual sales and little or no interstate commerce, and are operating under conditions that provide reasonable assurance that products are not adulterated. Where serious insanitary conditions are noted, state agencies inspect such establishments twice as frequently as those not experiencing insanitary conditions.

We do not agree that establishments have to remain in FDA's inventory subject to routine inspection based on such factors as consumer complaints, receipt of goods in interstate commerce, or the types of products they produce. Consumer complaints could be forwarded for follow-up to state agencies that are routinely inspecting food establishments. Also,

state agencies could advise FDA when their inspections identify manufacturers shipping adulterated products in interstate commerce or manufacturers whose products are frequently found to have bacterial or pesticide problems.

With further reductions in FDA's food sanitation inventory, reductions in workload may be possible. To the extent that this occurs and in view of FDA's responsibilities for inspecting firms in the drug, cosmetic, and medical device areas, FDA has an opportunity to review its current level of resources for food sanitation and consider how such resources might best be used.

Recommendations to the Secretary of Health and Human Services

We recommend that the Secretary direct the Commissioner of FDA to

- review the current inventory and determine the establishments that should be removed, considering state inspection frequency, policies, and results and interstate commerce and sales volume;
- in conjunction with state inspection agencies, begin developing a strategy for future inspection of establishments with a history of serious or very serious sanitation problems to help assure these establishments are in compliance with applicable food laws and regulations; and
- consider the current level and allocation of inspection resources devoted to the food sanitation programs and make appropriate adjustments recognizing the reduced inventory and extent of inspection coverage needed to adequately monitor food manufacturing establishments.

Agency Comments and Our Evaluation

HHS, in commenting on a draft of this report on December 10, 1985 (see app. VI), stated that FDA will continue to coordinate efforts with state and local agencies to reach a level of surveillance that will optimize food safety while best using limited resources. In this regard, HHS noted that FDA is undertaking an initiative to set more specific criteria upon which resources will be allocated for future inspections of food establishments.

HHS commented on each recommendation and identified a number of actions FDA has initiated or plans to initiate that address the recommendations. Regarding our first recommendation, HHS stated that FDA routinely updates the inventory based on such factors as the product made and the compliance history of that segment of the industry as well as the frequency of state inspections and other factors we identified. HHS said it does not believe that scarce resources should be spent at this time

to undertake a re-review of the inventory to further reduce the number of establishments listed in the inventory. HHS believes that such an effort would use more resources than it would save through the few inspections prevented. However, FDA has established a committee that will make recommendations on the allocation of resources based on such factors as establishment type, state inspectional coverage, levels of industry compliance, and cycles of coverage. The committee's recommendations are expected to be implemented in fiscal year 1987.

Responding to our second recommendation, HHS stated that work planning between FDA districts and individual states is a major activity throughout the year and that considering an establishment's past inspection and compliance history is an integral part of the process. HHS stated that FDA:

- Is taking steps to work closer with states, national associations, and regional affiliates in obtaining adoption of model codes and in developing data needed by the states and FDA.
- Is developing a computerized data bank to gather and provide data on chemical residues found in food products.
- Will make additional efforts to strengthen and formalize the process (with states) of identifying establishments with serious sanitation problems so that additional inspectional or compliance follow-up actions, or other appropriate and effective measures, are taken to remedy the problem.
- Will emphasize a system of cooperative work-sharing agreements between FDA and the states, including provisions for a regular review of mutual compliance problems, an exchange of information, and coordination of follow-up actions.

Regarding our third recommendation, HHS said that FDA:

- Has initiated a study of its State Contract Program to determine what changes are needed to assure that resources are channeled into the most appropriate and effective program areas where states have the capability and interest to perform contract inspections.
- Has reprogrammed 10 percent of its food inspectional resources from domestic to import coverage.

We believe that FDA's ongoing and planned efforts regarding its interactions with the states for inspecting food manufacturers with little or no interstate sales are a step in the right direction, and we are encouraged

that FDA has established a committee to recommend how future inspectional resources will be allocated. We believe that if these future allocations also consider the amount of interstate sales, estimated annual sales volume, and prior sanitation problems, many establishments already being routinely inspected by state governments will no longer have to be inspected by FDA.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 10 days from its issue date. At that time, copies will be sent to the cognizant Senate and House committees and subcommittees; the Secretary of HHS; the Commissioner of FDA; the Director, Office of Management and Budget; state agencies responsible for conducting food sanitation inspections; and other interested parties.

Sincerely yours,

Richard L. Fogel

Richard L. Fogel
Director

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Abbreviations

FDA	Food and Drug Administration
FD&C	Food, Drug, and Cosmetic
HHS	Department of Health and Human Services

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Objectives, Scope, and Methodology

At a June 12, 1984, meeting, Food and Drug Administration (FDA) officials agreed to review the 85 establishments with limited or no interstate sales and justify the basis for continued inspection of these establishments. On December 12, 1984, the Department of Health and Human Services (HHS) advised us that 69 of the 85 establishments should remain in FDA's inventory subject to routine inspection. Information provided by FDA officials showed that they deleted 16 establishments from the inventory. Some of these were retail stores or did not ship food products interstate.

FDA headquarters officials stated that state governments were not contacted to determine their inspection policies concerning the 69 establishments. As a result, our objective for this review was to determine the inspection policies of Puerto Rico and the 26 states[1] in which the 69 establishments were located, the frequency with which state agencies conduct routine food sanitation inspections, and the inspections such agencies had conducted for the 69 establishments during 1982, 1983, and 1984. Also, we wanted to determine if FDA could reasonably place greater reliance on the states for inspecting some firms in its inventory.

To obtain the above information, on December 20, 1984, two questionnaires were forwarded to the 26 states and Puerto Rico. All 27 agencies returned our questionnaires. One questionnaire asked the agencies (1) if they routinely conducted food sanitation inspections, and if so, if such inspections were required by state law or established by agency policy or regulation and (2) how frequently food establishments were required to be inspected.

The second questionnaire asked for specific data on the 69 establishments that FDA believed should continue to be routinely inspected. For example, the inspection agencies were asked to (1) determine whether the particular establishment was currently subject to inspection; (2) provide the establishment's estimated sales volume and percent of intrastate sales, if known; and (3) list the date of all inspections conducted during 1982, 1983, and 1984 and classify the extent of insanitary conditions found during such inspections according to the following criteria.

[1]California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Montana, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, and Wisconsin.

No Insanitary Conditions.

Minor Insanitary Conditions (not likely to cause product adulteration).

Serious Insanitary Conditions (could reasonably result in or have potential for causing product adulteration).

Very Serious Insanitary Conditions (have immediate potential or have caused product adulteration).

FDA used these criteria to classify the seriousness of insanitary conditions for the 152 inspections carried out at our request during 1983.

Information provided by the 27 inspection agencies on the 69 establishments showed that 10 establishments were not inspected. This was because

- 5 were subject to local or county inspection;
- 3 were no longer in business; and
- 2 were unknown to the state agency, although the agency indicated that these establishments would be inspected as soon as possible.

Of the remaining 59 establishments subject to state inspection, 57 were inspected 294 times, or an average of 5 times, during the 3-year period. Two firms were not inspected by the states during the 3-year period. One state agency advised us that 1982 inspection records were no longer available.

We also obtained information on the 59 establishments from FDA inspection records on the estimated sales volume, the estimated percentage of interstate sales, the types of products manufactured, and the results of FDA inspections. Between February and June 1983, FDA, at our request, had inspected these firms that were included in its inventory and subject to routine inspections. FDA gave us copies of inspection records for these firms.

Based on classification of sanitation information obtained from state agencies and FDA's inspections, we developed profile data on FDA and state inspections and results, interstate commerce, and sales volume for the 59 establishments. We also obtained and analyzed FDA's justification for keeping establishments in or deleting them from the inventory. We discussed our observations with FDA headquarters officials in the Office

of Regional Operations and the Center for Food Safety and Applied Nutrition.

Our work was performed in accordance with generally accepted government auditing standards.

State Agency Inspections and Results for Firms Remaining in FDA's Inventory

FDA's basis for keeping firm in inventory (categories)[a]	Number of firms	Number of state inspections	Insanitary conditions			
			None	Minor	Serious	Very serious
History of insanitary conditions	8	44	10	13	14	7
Possible bacterial and pesticide problems	9	35	3	23	6	3
Potential for problems because of products produced (cheese, butter, cream)	9	60	6	45	9	•
Interstate Milk Shippers Program[b]	6	61	11	48	2	•
Received products in interstate commerce	17	82	14	35	20	13
Labeling problems or color violations	6	16	4	11	1	•
Consumer complaints	7	20	8	10	2	•
Significant wholesale business	16	90	7	37	24	22
Products that are repacked and sold or distributed interstate by other firms	13	38	5	24	8	1
Large volume business and/or 20 percent or more interstate sales	8	37	14	18	5	•

[a]FDA cited several reasons for each firm that was to remain in its inventory. Therefore, firms may be included in more than one category.

[b]A voluntary cooperative federal/state effort aimed at assuring that the nation's milk supply is uniformly safe and wholesome.

State Inspections Grouped According to Sales Volume of Firm

Estimated sales volume of firms[a]	Number of firms	Number of state inspections	Insanitary conditions			
			None	Minor	Serious	Very serious
$0-$24,999	2	4	1	3	•	•
25,000-49,999	4	21	9	12	•	•
50,000-99,999	2	16	•	1	8	7
100,000-499,999	10[b]	36	5	27	4	•
500,000-999,999	9	46	4	22	9	11
1,000,000-4,999,999	21	101	22	58	17	4
5,000,000-9,999,999	7	45	2	34	9	•
25,000,000-49,999,999	2	15	7	8	•	•
50,000,000 plus	1[c]	•	•	•	•	•
Unknown	1	10	1	1	5	3
Total	**59**	**294**	**51**	**166**	**52**	**25**

[a]Obtained from FDA inspection reports.

[b]One firm subject to state inspection was last inspected by the state in 1981.

[c]Not inspected during 1982, 1983, or 1984.

Examples of Firms Remaining in FDA's Inventory Inspected by FDA and the States

Firm A. This firm has estimated sales of over $100,000 per year. FDA inspected the firm in 1982 and in 1983. Some objectionable conditions—a defective cooling unit and unshielded light fixtures—were noted during the 1982 inspection. No insanitary conditions were noted during the 1983 inspection.

Between February 1982 and November 1984 the state conducted 10 inspections. Five inspections indicated serious sanitation problems, and three, including the November 1984 inspection, indicated very serious problems. State inspectors closed the firm for "insanitary conditions with the provision that operator may reapply in 30 days if violations are corrected." State law requires inspection and annual license. Before issuing a license, the state must be satisfied with the firm's sanitation conditions. FDA justified continued inspection of the firm because it had over 50-percent wholesale business.

Firm B. This firm is a fruit juice manufacturer and apple repacker that has estimated sales of between $1 million and $5 million. The firm ships 5 percent of its finished products into interstate commerce. FDA inspected the firm at our request in May 1983 and found very serious sanitation problems. Apple juice contaminated with fruit flies was seized. Other objectionable conditions included unshielded light fixtures and poor employee health practices.

Management agreed to take corrective action. A 1981 FDA inspection noted exposed insulation and open and uncovered fruit juice tanks.

The state inspected the firm seven times between March 1982 and January 1984. Six inspections disclosed minor sanitation problems, and one found no problems. State law requires inspection and annual license. The state must be satisfied of the firm's sanitation conditions before issuing a license. FDA stated that the firm should remain in its inventory because of a violative history.

Firm C. This firm is a soft drink bottling company with estimated sales of between $1 million and $5 million. An FDA inspection report indicated that the firm has stopped direct interstate distribution and receives its principal beverage bases from within the state. FDA inspected the firm in 1981 and found no sanitation problems. A March 1983 inspection noted minor problems. An FDA inspection report indicated the firm has not had sanitation problems over the past 5-1/2 years.

The state has inspected the firm five times between October 1982 and August 1984. Three inspections, including the latest, did not disclose any sanitation problems. Two others revealed minor and serious insanitary conditions. State law requires a yearly inspection. FDA stated that the firm should remain in the inventory because it receives goods in interstate commerce and has been subject to consumer complaints.

Firm D. This firm is a bottling company that was inspected by FDA in March 1983. Minor sanitation problems, such as flaking paint and mold, were found. The state inspected the firm four times between June 1983 and November 1984. Three of these inspections found no sanitation problems, and one noted minor problems. The firm does between $1 million and $5 million in sales; all soft drinks are sold intrastate within a 50-mile radius of the company.

State law requires inspection of food firms but does not specify frequency. Inspection intervals are based on the type of product and the history of operations. FDA advised us that the firm is subject to consumer complaints and receives goods in interstate commerce and, therefore, should remain in the inventory.

Firm E. This company produces canned soft drinks with estimated sales volume between $25 million and $50 million and 10-percent interstate sales. An FDA inspection in April 1983 found no sanitation problems. The state inspected the firm nine times between October 1982 and October 1984. Two of these inspections noted minor sanitation problems, and the other seven found no problems. The state policy is to inspect firms once every 3 months. FDA kept the firm in its inventory based on the large volume of business and the firm's 10-percent interstate sales.

Firm F. This bakery was inspected by FDA in April 1982 (no sanitation problems) and March 1983 (minor problems). The state inspected the firm nine times between January 1983 and September 1984. The first two inspections identified serious sanitation problems, the next six identified minor problems, and the latest revealed no problems. An FDA inspection report indicated that the firm distributes its products within a 25-mile radius with no interstate sales. The report indicated that about 27 percent of the bakery's business was through a small shop in front of the store. Estimated sales for the bakery are between $100,000 and $500,000. State agency policy requires an inspection every 3 months. FDA justified keeping the firm in its inventory because of its wholesale business.

Firm G. This bakery was inspected by FDA in April 1983, and minor problems, such as unshielded lights and uncovered products, were noted. A previous inspection, done under an FDA contract by the state, found rodent problems. The state conducted seven inspections between June 1982 and September 1984—four noted very serious sanitation problems and three noted serious problems. Sales are estimated at between $50,000 and $100,000. The firm sells products through a retail outlet and to restaurants and butcher shops. The FDA inspection report indicated no interstate sales.

State law and agency policy require food sanitation inspections as "needed." FDA stated that because the firm has had a history of sanitation problems and does 100-percent wholesale business, it should remain in the inventory.

Firm H. This seafood firm was inspected by FDA in November 1981 (no sanitation problems) and March 1983 (minor sanitation problems). The state inspected the firm nine times between February 1983 and December 1984. Of these inspections, three identified very serious sanitation problems, five noted serious problems, and the latest noted minor problems. Sales are estimated between $1 million and $5 million with 1-percent interstate sales.

State inspection agency policy is to inspect firms every 3 months. FDA stated that the firm should remain in its inventory because it presents bacterial hazards.

Firm I. FDA inspected this firm, which produces cheese, in 1982 and 1983, with both inspections identifying minor sanitation problems. The state conducted 10 inspections between November 1982 and October 1984—6 inspections noted minor sanitation problems, and 4 identified serious problems. A March 1983 FDA inspection report indicated sales between $5 million and $10 million with 10-percent interstate sales.

State regulation requires inspections once a year but twice a year for hazardous firms. FDA advised us that the firm does 50-percent interstate business and, therefore, should remain in its inventory.

Firm J. This company, which has an estimated sales volume between $500,000 and $1 million, operates as a neighborhood bakery. It sells bread over the counter and to restaurants (about 15 percent). The company receives 95 percent of its raw materials from another intrastate

firm. A 1983 FDA inspection revealed minor insanitary conditions due to rubbish around the bakery.

Food manufacturing establishments are required by law to be inspected every 6 months by the state agency. The agency inspected this bakery nine times between March 1982 and September 1984. All nine inspections identified very serious sanitation problems. FDA stated this company should remain in its inventory because it receives products in interstate shipment and does 15-percent wholesale business.

Questionnaires Concerning State Inspections of Food Manufacturing Establishments

U.S. GENERAL ACCOUNTING OFFICE

Information Concerning Agency Inspections
Of Food Manufacturing Establishments

1. Is the food manufacturing establishment named above currently subject to routine sanitation inspections by your health agency or has it been subject to such inspections in the past?

   1. [ ] Yes, it is currently subject to inspections (GO TO QUESTION 4)
   2. [ ] Yes, it was subject to inspection but has gone out of business
   3. [ ] No, it was never subject to inspection

2. Please explain why the specific food manufacturing establishment named above was never subject to inspection by your agency.

   _____

   _____

   _____

3. If the food manufacturing establishment named above was never subject to inspections by your agency or has gone out of business please disregard the remaining questions concerning this manufacturing establishment and return this form in the envelope provided.

4. Does the food manufacturing establishment named above operate on a year-round basis or does it operate only during specific seasons of the year? (PLEASE CHECK ONE.)

   1. [ ] Year-round
   2. [ ] Seasonal
   3. [ ] Unknown

5. What is the current annual sales volume for the food manufacturing establishment? (PLEASE CHECK ONE.) (IF UNKNOWN, PLEASE CHECK THIS BOX [ ].)

   1. [ ] Under $25,000
   2. [ ] $25,000 to under $50,000
   3. [ ] $50,000 to under $100,000
   4. [ ] $100,000 to under $500,000
   5. [ ] $500,000 to under $1,000,000
   6. [ ] $1 million to under $5 million
   7. [ ] $5 million to under $10 million
   8. [ ] $10 million to under $25 million
   9. [ ] $25 million to under $50 million
   10. [ ] $50 million or over

6. About what percent of the manufacturer's sales were made in your state (intrastate). (IF UNKNOWN PLEASE CHECK THIS BOX [ ].)

   _____%

7. Please list the main food products manufactured by the above establishment.

   _____

8. Has the establishment named above been inspected by your agency during calendar year 1982, 1983 or 1984? (CHECK ONE.)

   1. [ ] Yes (GO TO QUESTION 9 ON THE OTHER SIDE.)
   2. [ ] No (FORM COMPLETED.)

9. Please list the dates of all sanitation inspections your agency conducted at the previously named food manufacturing establishment during calendar years 1982, 1983, and 1984 beginning with the most recent and going back to the earliest. In addition, for each inspection please indicate by checking the appropriate column whether the inspection disclosed: (1) no insanitary conditions, (2) minor insanitary conditions, (3) serious sanitary conditions, or (4) very serious sanitary conditions, as these categories are defined in the column headings. (PLEASE CHECK ONE COLUMN FOR EACH INSPECTION.)

	Extent of Insanitary Conditions Found During Inspection (CHECK ONE FOR EACH INSPECTION)			
Date of Inspection	NONE (1)	MINOR (not likely to cause product adulteration) (2)	SERIOUS (could reasonably result in or have potential for causing product adulteration) (3)	VERY SERIOUS (have immediate potential or have caused product adulteration) (4)
MTH. DAY YEAR ____/____/____				
____/____/____				
____/____/____				
____/____/____				
____/____/____				
____/____/____				
____/____/____				
____/____/____				
____/____/____				

U.S. GENERAL ACCOUNTING OFFICE

Information Concerning State Inspection Policies

1. Does your agency routinely conduct sanitation inspections of food manufacturing establishments located in your state? (CHECK ONE.)

   1. [ ] Yes

   2. [ ] No

2. Is the practice of routine inspection of establishments required by state law or simply established by agency regulation or policy? (PLEASE CHECK ONE.)

   1. [ ] Required by state law

   2. [ ] Established by agency regulation or policy

   3. [ ] Other (PLEASE SPECIFY.) _____

      _____

3. How frequently is each such establishment required to be inspected by your agency? (PLEASE CHECK ONE.)

   1. [ ] One every three months

   2. [ ] One every six months

   3. [ ] Once a year

   4. [ ] Once every two years

   5. [ ] Once every three years

   6. [ ] Other (PLEASE SPECIFY.) _____

      _____

4. Person we may contact for additional information if necessary.

   Name: _____

   Telephone number: _____

5. If you have any additional comments concerning your agency's responsibilities regarding the inspection of food manufacturing establishments please provide them in the space provided below. Attach an additional sheet if necessary.

Advance Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

Mr. Richard L. Fogel
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report, "Follow-up on Prior Report Concerning the Food and Drug Administration's (FDA's) Inspection of Food Manufacturing Establishments." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "FOLLOW-UP ON PRIOR REPORT CONCERNING THE FOOD AND DRUG ADMINISTRATION'S (FDA'S) INSPECTION OF FOOD MANUFACTURING ESTABLISHMENTS," REPORT NO. HRD-86-2 DATED NOVEMBER 1, 1985

General Comments

We appreciate having the opportunity to review and comment on the General Accounting Office's (GAO's) draft report. This report is a follow-up of certain issues raised in the 1984 GAO report. FDA has continued to consider the best means of managing its field inspection activities and to improve the program. Monitoring sanitation in the food industry remains a priority for FDA. Currently, FDA has the capability for monitoring such foodborne biological hazards, which many states and local governments lack. FDA continues to coordinate efforts with state and local agencies to reach a level of surveillance afforded food establishments that will optimize food safety while making the best use of limited resources. To this end, FDA is undertaking an initiative to set more specific criteria upon which resources will be allocated for future inspections of food establishments that are part of the Official Establishment Inventory (OEI).

We have the following comments on GAO's three recommendations.

GAO Recommendation

We recommend that the Secretary direct the Commissioner of FDA to:

1. --review the current inventory and determine those establishments that should be removed considering state inspection frequency, policies, and results and interstate commerce and sales volume.

Department Comment

FDA routinely updates the OEI on the basis of factors such as the product made and the compliance history of that segment of the industry, as well as the frequency of state inspections and the other factors identified by GAO.

Since FY 1981, FDA has undertaken several initiatives to improve the maintenance of the OEI. As a result, the total active OEI for all establishments subject to FDA jurisdiction has been reduced from some 140,000 to 97,000, of which approximately 60,000 are food

establishments. Establishments not in the active OEI are placed in an auxiliary file and no resources are planned for routine coverage of these firms.

We do not believe that scarce resources should be expended at this time to undertake a re-review of the OEI to further reduce the number of food establishments listed in the active OEI. Such an effort would be more resource intensive than the savings realized from the few inspections prevented. FDA has established a committee that will make recommendations on the allocation of resources based on such stratification factors as: establishment type (manufacturer or repacker), state inspectional coverage, levels of industry compliance and cycles of coverage. We expect the recommendations from this committee to be implemented in FY 1987.

GAO Recommendation

2. --begin developing a strategy, in conjunction with state inspection agencies, for further inspection of establishments with a history of serious or very serious sanitation problems to help assure these establishments are in compliance with applicable food laws and regulations.

Department Comment

This is an on-going activity. For many years, FDA has had a close working relationship with counterpart state agencies both in the field and at headquarters. In the early 1960s, FDA began a program of actively seeking a more formal approach to workplanning and worksharing. These early efforts resulted in a number of letters of agreement and memoranda of understanding (MOU). In the early 1970s, as a result of the GAO study of FDA's food sanitation program, we received, among other increases, authorization from Congress to begin the FDA-State Contract Program. There are currently 37 states that have contracts with FDA in the food sanitation area. In addition, FDA District Offices have formal MOUs with 18 states covering a variety of regulatory concerns. A number of the other states that have not entered into FDA contracts or MOUs for food sanitation activities may not have strong food regulatory programs. Further, they have demonstrated no interest in a contract covering food establishments or in entering into a voluntary workplanning agreement with FDA.

Workplanning between the FDA districts and individual states is a major activity throughout the year. To eliminate redundancy of coverage, FDA and State officials review the OEI to coordinate efforts and determine their respective areas of primary responsibility. Consideration of the past inspection and compliance history of an establishment is an integral part of the process.

FDA inspection results are shared with states and follow-up actions to consumer complaints are developed with state agencies to assure appropriate interaction. In workplanning, FDA also works through national associations and regional affiliates such as the National Association of State Departments of Agriculture and the Association of Food and Drug Officials. We are taking steps to assure that more use is made of their assistance in obtaining the adoption of model codes and in developing data needed by states and FDA. For example, FDA is developing a computerized data bank to gather and provide data on chemical residues found in food products based on data supplied by states and industry with the American Association of Feed Control Officials.

We agree that the identification of establishments warranting additional inspectional or compliance follow-up actions to serious sanitation problems is appropriately accomplished at the local level between an FDA district and the individual state. Depending upon the nature of the problem in a particular establishment, a joint inspection may be scheduled or a more effective remedy selected within the various Federal or State sanctions available. While this type of coordination is currently being accomplished, additional efforts will be made to strengthen and formalize the process.

FDA's strategy will be to continue to build on the cooperative efforts already undertaken and to emphasize a system for cooperative worksharing agreements with the states. One of the standard provisions of the agreements will be the regular review of mutual compliance problems, exchange of information, and coordination of follow-up actions. This type of effort is endorsed by the Association of Food and Drug Officials, and we will continue to consult with them in the implementation of these agreements.

In summary, we have made considerable progress in Federal/State cooperative efforts in the coverage of the food industry and FDA will continue to ensure that these efforts include coverage of establishments with a history of serious or very serious sanitation problems.

GAO Recommendation

3. --consider the current level and allocation of inspection resources devoted to the food sanitation programs and make appropriate adjustments recognizing the reduced inventory and extent of inspection coverage needed to adequately monitor food manufacturing establishments.

Department Comment

Reference our comments on the first recommendation. FDA already considers these factors in allocating its limited inspection resources and will continue to make adjustments as needed. FDA has initiated a study of the State Contract Program to determine what changes are needed to assure that resources are channeled into the most appropriate and effective program areas where states have the capability and interest to perform contract inspections.

Also, in FY 1986, FDA has reprogrammed ten percent of the food inspectional resources from domestic to import coverage. We believe this is a sound decision at the present time because of the level of consumer protection achieved through joint Federal/State coverage of the domestic food industry.

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